5. 510 (K) SUMMARY

K072514

SEP 21 2007

510 (k) SUMMARY
(per 21 CFR §807.92)

VISULAS Trion

GENERAL INFORMATION

Name and Address of the Applicant:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany Est. Reg. No. 9615030
Official Correspondent:	Kent W. Jones Vice President, RA/CA/QA/Compliance Carl Zeiss Meditec Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4353 (phone) (925) 557-4481 (fax)
Classification name:	Laser Instrument, Surgical, Powered
Classification:	Class II (acc. 21 CFR 878.4810)
Product Code:	GEX
Trade/Proprietary name:	VISULAS Trion

PREDICATE DEVICE

Company: Device:	Carl Zeiss Meditec AG VISULAS 532s (K013402)
Company: Device:	Lumenis Novus® Varia™ Ophthalmic Laser and Delivery Devices (K022181)
Company: Device:	Nidek Multi Color Laser Photocoagulator Model MC-300 (K042785)

INTENDED USE

The VISULAS Trion is intended for use in photocoagulating ocular tissues for the treatment of diseases of the eye, such as:

- Photocoagulation of the retina
- Trabeculoplasty for treatment of glaucoma
- Iridotomy for treatment of glaucoma.

The laser energy is delivered via either transpupillary delivery or intraocular endoprobe delivery.

DEVICE DESCRIPTION

The VISULAS Trion is a diode-pumped, solid state, three-color laser system for green, yellow and red wavelengths, based upon the predicate VISULAS 532s (K013402). The VISULAS Trion laser system consists of the following components: Laser console as the source of laser radiation with detachable operating control panel, two fiber ports for application devices and a foot switch. Application devices for laser radiation delivery are offered via either transpupillary or intraocular delivery, laser slit lamp, laser indirect ophthalmoscope and endoprobes.

SUBSTANTIAL EQUIVALENCE

The VISULAS Trion is substantially equivalent to the predicate devices identified previously. The VISULAS Trion is substantially equivalent to the predicate devices with regard to intended use, operating principle, function, and materials.

Evaluation performed on the VISULAS Trion supports the indications for use statement and demonstrates the device is substantially equivalent to the predicate devices and does not raise new questions regarding safety and effectiveness.

SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on the VISULAS Trion to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2007

Carl Zeiss Meditec AG
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street
Buffalo, MN 55313

Re: K072514
Trade/Device Name: VISULAS Trion
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 6, 2007
Received: September 7, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: VISULAS Trion

Indications for Use: The VISULAS Trion is intended for use in photocoagulating ocular tissues for the treatment of diseases of the eye, such as:

- Photocoagulation of the retina
- Trabeculoplasty for treatment of glaucoma
- Iridotomy for treatment of glaucoma.

The laser energy is delivered via either transpupillary delivery or intraocular endoprobe delivery.

Prescription Use __x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072514